IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re.:

Heparin Products Liability Litigation — MDL No. 1953

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Robert Yeazel, etc.,

Plaintiff — Case No.1:09HC60186

v. — **ORDER**

Baxter Healthcare Corporation, *et al.*,

Defendants

This is a suit arising from alleged administration of contaminated heparin, which the Judicial Panel on Multi-District Litigation has referred to the undersigned.

Pending is plaintiff's motion for clarification (Doc. 89) of a potion of an opinion entered July 21, 2011. *In re Heparin Products Liability Litigation*, --- F.Supp.2d ----, 2011 WL 2971918 (N.D. Ohio). The motion seeks "clarification" of the following portion of that opinion:

> Plaintiffs have put forth no reliable evidence of injuries resulting from non-bolus doses. Though there is evidence that contaminated heparin can cause a variety of adverse events, defendants are correct that the epidemiological studies indicate bolus doses, rather than other routes and dose amounts, as being associated with adverse events.

— F.Supp.2d at —, 2011 WL 2971918, *37.

In essence, plaintiff's motion for clarification, as defendants contend, actually seeks reconsideration of the conclusion excluding, on *Daubert* grounds, plaintiffs' proffered evidence that intravenous non-bolus doses of contaminated heparin could cause injury.

As a predicate to his request for reconsideration, plaintiff sees confusion on my part as to the distinction between bolus and non-bolus doses. He asserts that I used the term "bolus" as a synonym applicable to all forms of subcutaneous or intravenous injection of heparin. In support of this contention – which, to the extent plaintiff's motion actually seeks clarification, this does – plaintiff cites the following passage from my opinion:

> The pending summary judgment motion seeks dismissal of claims of injury or death where the allegedly causative reactions are outside the CDC case definition parameters. These reactions include HIT, bleeding or clotting, sepsis, injuries with a time to onset greater than one hour after administration of contaminated heparin, and injuries involving nonbolus dosing *or subcutaneous administration rather than intravenous administration*.

(Doc. 89-1, pg. 3 (citing 2011 WL 2971918, *4)) (emphasis supplied).

Plaintiff also detects confusion on my part in this statement: "Plaintiffs have put forth no reliable evidence of injuries resulting from non-bolus doses. . . . Having found the testimony of Dr. Hoppensteadt *on subcutaneous dosage* unreliable, I cannot accept plaintiffs' argument that the FDA recalls of all contaminated products indicates that non-bolus doses can cause injury." (*Id.* (citing 2011 WL 2791918, *37)) (emphasis supplied).

The phrasing of these two passages was, at best, inartful, and might, standing alone, possibly have been confusing to an uniformed reader.

A fair reading of the entirety of the opinion, however, makes clear, I am confident, that I in fact understood and understand the distinction between bolus (sudden and substantial) and non-bolus (protracted, slow and low) administration, though each can be delivered subcutaneously.[1]

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[1] Even within the quoted passage my meaning was clear – though plaintiff's motion for clarification disingenuously substitutes ellipses for the following statement: "Though there is evidence that contaminated heparin can cause a variety of adverse events, defendants are correct that the epidemiological studies indicate bolus doses, *rather than other routes and dose amounts*, as

To the extent the plaintiff's motion truly seeks clarification of my opinion on the basis of these two statements, I trust the discussion so far suffices to resolve any confusion on his part.

Using those two passages as a springboard, plaintiff's motion seeks to go further, and to accomplish its actual objective. Namely, to obtain, not "clarification," but reconsideration and reversal of my conclusion that plaintiffs in the MDL failed to meet the *Daubert* requirements as to injury from non-bolus doses of contaminated heparin.

At issue, as it was in the *Daubert* hearings resulting in that conclusion, which I herewith confirm, is general causation: *i.e.* under what conditions is it probable that administration of contaminated heparin would cause injury.

In Ohio, proof of causation requires expert testimony. *See, e.g., Roberts v. Ohio Permanente Med. Group, Inc.*, 76 Ohio St.3d 483, 485 (1996) (medical-malpractice claim requires plaintiff to "prove causation through medical expert testimony in terms of probability to establish that the injury was, more likely than not, caused by the defendant's negligence.").

That something is possible, or that it might happen is, however, insufficient:

> It is well-settled that the establishment of proximate cause through medical expert testimony must be by probability. At a minimum, the trier of fact must be provided with evidence that the injury was more likely than not caused by defendant's negligence. Opinions expressed with a lesser degree of certainty must be excluded as speculative.FN3
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> > FN3. "Proof of possibility is not sufficient to establish a fact; probability is necessary. * * * ". "Probable is more than 50% of actual. * * * " Evidence which only shows that a condition could have been the result of an injury is "insufficient proof to warrant submission of the cause to the jury. * * * "
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> The evidence seeking to causally connect appellee's pancreatic cancer to his exposure to [the substance at issue] was merely speculative and conjectural, and did not rise to the requisite standard of probability.

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being associated with adverse events." 2011 WL 2791918, *37. (Emphasis supplied).

Shumaker v. Oliver B. Cannon & Sons, Inc., 28 Ohio St.3d 367, 369 (1986) (citations omitted).

Plaintiff supports his renewed contention that the record shows he can meet this standard. He cites references to conclusions, most of which were reached in the early stages of the investigation which got underway after an outbreak of post-heparin adverse event reports. At most, these references support the conclusion that intravenous injection of non-bolus doses of contaminated heparin *might* lead to the effects and injuries similar to those associated with bolus-dosage of contaminated heparin. Those references do not, in light of later-developed evidence, withstand the law's demand for more strenuous and scientifically reliable proof.

That proof does not exist, as even plaintiff's own experts admitted at the *Daubert* hearing. Thus, Dr. Burcher testified:

> Q. Okay. And so you would agree that there's no study that has shown that contaminated heparin administered in non-bolus doses is more likely than not associated with any adverse events?
>
> * * * * *
>
> A. I do not know such a study at this time.

Dr. Hoppensteadt, whose testimony as to other issues I found met the *Daubert* standard, likewise similarly agreed:

> Q. And there's no study or data demonstrating that patients who did not receive a bolus dose of contaminated heparin had a statistically significant increased risk of injury or disease, correct?
>
> * * * * *
>
> A. Since there's no reports about – then there's no reports on that either, correct.

Moreover, the conclusion that adverse reactions from contaminated heparin are limited to bolus doses is well supported. According to the FDA, "severe hypotension [was found] in association with the use of intravenous bolus doses of heparin." The agency also observed that "[t]he increase in occurrence of adverse events with Baxter's heparin appears to be related to administering

large amounts of the heparin product over a very short time. An increase in serious reactions has not been seen with use of small amounts and/or slow infusions of heparin sodium."

Consequently, other uses of heparin, FDA stated, were "not of concern":

> Heparin is used in many other medical settings, but these do not usually require the higher doses that are of concern with the Baxter product. Other uses which are not of concern include small doses of heparin used to flush, clear out, intravenous catheters to prevent clotting in indwelling catheter, and slow heparin infusions to treat clotting in various hospital settings.

Notably, the FDA did not distinguish between intravenous and non-intravenous administrations, as advocated by plaintiff. Rather, the FDA specifically contrasted "intravenous bolus doses" with the use of "small amounts and/or slow infusions of heparin sodium" – *i.e.*, non-bolus doses.

Plaintiff claims in his motion that "none of the experts in this litigation have offered an opinion that a bolus dose of contaminated heparin is required to cause injury." (Doc. 89-1, pg 5). The report by plaintiff's own expert, Dr. Parisian refutes this claim. She stated that the FDA "reiterated a message that adverse events had been reported associated with administration of a rapid bolus infusion of heparin." As Dr. Parisian also noted, when the FDA issued its recall notification it specifically encouraged use of heparin in non-bolus doses. The agency did so because "the adverse reactions we are seeing are related to bolus dosing." Thus, the FDA cautioned, "healthcare professionals should administer the drug as an intravenous infusion not a bolus dose whenever possible." Others, including Dr. Luke, Dr. Hoppensteadt, and Nurse Hubley, all referenced boluses when discussing contaminated heparin reactions.

There was more than adequate support for my conclusions that: 1) the record with regard to injury from non-bolus intravenous administration of contaminated heparin is insufficient; and 2) only when administered in a bolus dose is injury possible.

Conclusion

To the extent (which was minimal, if that) that my original opinion needed any clarification, I trust the foregoing meets that need.

I trust as well that the foregoing satisfies the actual purpose of the pending motion, which was to have me reconsider my decision that only bolus doses of contaminated heparin posed a risk of injury.[2]

It is, accordingly,

ORDERED THAT on reconsideration, the prior ruling that there is no reliable evidence of injuries resulting from non-bolus doses of heparin be, and the same hereby is confirmed.

So ordered.

/s/ James G. Carr
Sr. United States District Judge

[2] While there is substantial merit to defendants' contentions that plaintiff's motion comes within Fed. R. Civ. P. 59, and thus is untimely, rather that Rule 60, on which it purports to rest, I prefer to consider plaintiff's arguments on their merits.

In this instance, I will not impose sanctions (in this court, normally, $2,000 as an for attorneys' fees and costs, unless the prevailing opponent seeks and justifies a higher award – which here would appear to be merited). I expect not to be as charitable when and if I overrule other motions for reconsideration, regardless of how counsel may caption them.